

SAFETY DATA SHEET

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH) & 1272/2008 (CLP)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier	Trade name	PEEK-CLASSIX[®] BC1-BK, BC2-BK and BC3-BK Granules and Stockshapes.
	CAS No.	Polyaryletherketone 31694-16-3 or 29658-26-2 Carbon Black 1333-86-4
	EINECS No.	Polyaryletherketone Not available Carbon Black 215-609-9
	REACH Registration No.	Not available
1.2 Relevant identified uses of the substance or mixture and uses advised against	Identified use(s)	The material is designed for medical device applications requiring blood or tissue contact for less than 30days. The materials are generally used for injection moulding and extrusion operations.
	Uses advised against	This material is not for long term implantation.
1.3 Details of the supplier of the safety data sheet	Company Identification	Invibio Ltd Technology Centre Hillhouse International, Thornton-Cleveleys Lancs, UK FY5 4QD
	Telephone	++ 44 (0) 1253 866812
	Fax:	++ 44 (0) 1253 851458
	E-Mail (competent person)	sds@invibio.com
1.4 Emergency telephone number	Emergency Phone No.	++ 44 (0) 1253 866812

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture	Preparation is not classified as hazardous in the sense of directive 1999/45/EC and 2006/121/EC.
2.1.1 Regulation (EC) No. 1272/2008 (CLP)	Not classified as dangerous for supply/use.
2.1.2 Directive 67/548/EEC & Directive 1999/45/EC	Not classified as dangerous for supply/use.
2.2 Label elements	None.
2.3 Other hazards	None.
2.4 Additional Information	

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

EC Classification No. 1272/2008

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	Hazard statement(s)
None.	-	-	-	-

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	%W/W	EC No.	REACH Registration No.	EC Classification and Risk Phrases
None.	-	-	-	-

3.2 Additional Information

For full text of H/P phrases see section 16.

SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

Inhalation

Remove to fresh air and keep at rest in a position comfortable for breathing.

Skin Contact

After contact with skin, wash immediately with plenty of soap and water. In the event of contact with molten product: Cool affected area quickly with water. Do not attempt to remove hardened product. Obtain medical attention.

Eye Contact

Flush eyes with water for at least 15 minutes while holding eyelids open.

Ingestion

Call a physician (or poison control centre immediately). Do not induce vomiting wash out mouth with water. Call a physician (or poison control centre immediately).

4.2 Most important symptoms and effects, both acute and delayed

Unlikely to be required but if necessary treat symptomatically.

4.3 Indication of the immediate medical attention and special treatment needed

Unlikely to be required but if necessary treat symptomatically.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

Extinguish with waterspray, foam or dry chemical.

Unsuitable Extinguishing Media

None.

5.2 Special hazards arising from the substance or mixture

In case of fire the following can develop: Oxides of carbon.

5.3 Advice for fire-fighters

A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

Dust is ignitable but will not sustain combustion. A high temperature source of ignition is required. Insensitive to sparks. It will not train fire, e.g. along beams etc.

SECTION 6: ACCIDENTAL RELEASE MEASURES

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| 6.1 Personal precautions, protective equipment and emergency procedures | Avoid inhalation and contact with eyes or skin. Ensure sufficient supply of air. Avoid build up of dust. Remove possible cause of ignition – do not smoke. Take precautionary measures against static discharge. |
| 6.2 Environmental precautions | Avoid release to the environment. Prevent surface and ground water infiltration, as well as ground penetration. |
| 6.3 Methods and material for containment and cleaning up | Sweep up carefully with non-sparking tools. Transfer to a lidded container for disposal or recovery. Avoid build up of dust. |
| 6.4 Reference to other sections | |
| 6.5 Additional Information | |

SECTION 7: HANDLING AND STORAGE




- | | |
|---|--|
| 7.1 Precautions for safe handling | <p>General hygiene measures for the handling of chemicals are applicable. Eating, drinking, smoking, as well as food storage, is prohibited in work room. Avoid build up of dust. Local Exhaust Ventilation at the workplace or on the processing machines required. Note: Danger of explosive dust</p> <p>Machine Cleaning (purging): Purging with other polymers (e.g Polyethylene) at high temperatures can be hazardous. Auto ignition may also occur. Local exhaust ventilation is required. The relevant Safety Data Sheet for the purge material to be used should be consulted. Additional information can be obtained from the Victrex website www.victrex.com</p> |
| 7.2 Conditions for safe storage, including any incompatibilities | <p>Store products enclosed, in original packing. The chemical structure and highly stable nature of PEEK-CLASSIX[®] polymers are such that the polymer's properties will not be affected by aging at ambient temperatures.</p> <p>Ambient
Providing product is suitably stored (dry storage avoiding extensive exposure to direct sunlight) and remains packaged in its original form, PEEK polymers will remain stable and therefore may be stored for extended periods of time prior to use. Tests have shown that polymer viscosity remains stable over a period of up to 20 years.</p> |
| <p>Storage Temperature
Storage Life</p> <p>Incompatible materials</p> | <p>None known</p> |
| 7.3 Specific end use(s) | The materials are generally used for injection moulding and extrusion operations. |

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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|---|------|
| 8.1 Control parameters | |
| 8.1.1 Occupational Exposure Limits | None |

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m ³)	STEL (ppm)	STEL (mg/m ³)	Note:
Dust. (general dust limit value)	-	-	10			Inhalable Dust
			4			Respirable Dust.

- | | |
|-------------------------------------|----------------|
| 8.1.2 Biological limit value | None |
| 8.1.3 PNECs and DNELs | Not available. |

8.2 Exposure controls	
8.2.1 Appropriate engineering controls	Local Exhaust Ventilation at the workplace or on the processing machines required.
8.2.2 Personal protection equipment	
Eye/face protection	Eye protection with side protection (EN 166)
	
Skin protection (Hand protection/ Other)	Impervious Gloves. Plastic or synthetic rubber gloves Additional information on hand protection – No tests have been performed.
	
Respiratory protection	When dealing with heated material: Insulating gloves EN 407 (heat) If above exposure limits are likely to be exceeded, breathing mask with fine dust filter (EN 143)
	
8.2.3 Environmental Exposure Controls	No special requirements.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties	
Appearance	Solid. (Granulate, Rod or Plate)
Colour	Black
Odour	Odourless
Odour Threshold (ppm)	None
pH (Value)	Not applicable
Melting Point (°C) / Freezing Point (°C)	343°C
Boiling point/boiling range (°C):	Not known.
Flash Point (°C)	Not known.
Evaporation rate	Not known.
Flammability (solid, gas)	Solid , Non-flammable
Explosive limit ranges	Not explosive.
Vapour Pressure (Pascal)	39.6 (@107°C)
Vapour Density (Air=1)	Not known
Bulk Density (g/ml)	~1.3
Solubility (Water)	Insoluble
Solubility (Other)	Insoluble
Partition Coefficient (n-Octanol/water)	Not known
Auto Ignition Temperature (°C)	595°C
Decomposition Temperature (°C)	> 450°C
Viscosity (mPa.s)	Not known
Explosive properties	Not explosive, May form explosive dust clouds in air.
Oxidising properties	Not oxidising
9.2 Other information	None

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	Stable under normal conditions.
10.2 Chemical stability	Stable under normal conditions.
10.3 Possibility of hazardous reactions	Stable under normal conditions.
10.4 Conditions to avoid	Stable under normal conditions.
10.5 Incompatible materials	Concentrated Sulphuric acid
10.6 Hazardous Decomposition Product(s)	Oxides of carbon

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.1 Substances

This product is essentially inert and non-toxic. Where appropriate the material has been tested in accordance with the following tests:

ISO 10993 – 1 Guidance

ISO10993 – 5 Cytotoxicity

ISO10993 – 10 Sensitisation

Please contact Invibio Ltd for details

Acute toxicity

Ingestion

Predicted to be low toxicity under normal conditions of handling and use.

Inhalation

Mechanical irritation of the respiratory tract.

Skin Contact

Repeated and/or prolonged skin contact may cause irritation. In the event of contact with molten product: Thermal Burns (molten polymer will adhere to skin and cause severe burns).

Eye Contact

No data. Dust may have irritant effect on eyes.

Permanent damage is unlikely.

Hazard label(s)

Not known

Serious eye damage/irritation

Not known

respiratory or skin sensitization

Not known

Mutagenicity

Not known

Carcinogenicity

Not known

Reproductive toxicity

Not known

STOT-single exposure

Not known

STOT-repeated exposure

Not known

Aspiration hazard

Not known

11.1.2 Mixtures

Not applicable

11.2 Other information

None

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Low toxicity to aquatic organisms.

12.2 Persistence and degradability

Not readily biodegradable.

12.3 Bioaccumulative potential

Not classified as PBT or vPvB.

12.4 Mobility in soil

The product has low mobility in soil. The product has low mobility in sediment.

12.5 Results of PBT and vPvB assessment

Not classified as PBT or vPvB.

12.6 Other adverse effects

None anticipated

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	Disposal should be in accordance with local, state or national legislation.
13.2 Additional Information	Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company. The waste codes are recommendations based on the scheduled use of this product. For alternative uses and applications, other waste codes may be allocated under certain circumstances. 07 02 13- waste plastic 07 02 99- waste not otherwise specified

SECTION 14: TRANSPORT INFORMATION

14.1 Land transport (ADR/RID) UN number Proper Shipping Name	Not classified as dangerous for transport. Not applicable Not applicable
14.2 Sea transport (IMDG) UN number Proper Shipping Name	Not classified as dangerous for transport. Not applicable Not applicable
14.3 Air transport (ICAO/IATA) UN number Proper Shipping Name	Not classified as dangerous for transport. Not applicable Not applicable
14.4 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	Not classified as dangerous for supply/use.
15.1.1 EU regulations Authorisations and/or restrictions on use	Observe restrictions VOC 1999/13/EC None
15.1.2 National regulations	None
15.2 Chemical Safety Assessment	Not relevant for this material.

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements: 1-16.

LEGEND

LTEL	Long Term Exposure Limit
STEL	Short Term Exposure Limit
STOT	Specific Target Organ Toxicity
DNEL	Derived No Effect Level
PNEL	Predicted No Effect Concentration

References:

Workplace Exposure Limit (UK HSE EH40)

Risk Phrases and Safety Phrases

None

Hazard statement(s) and Precautionary statement(s)

None

Training advice:

www.victrex.com

Additional Information

Manufactured in the UK under a Quality System approved to ISO 9001.

Additional information on the properties, processing and application of INVIBIO® polymers is available at www.invibio.com
These details refer to the product as it is delivered.

The statements made here should describe the product with regard to the necessary safety precautions – they are not meant to guarantee definite characteristics – but they are based on our present up-to-date knowledge.

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